

REMARKS

Claims 1-36 constitute the pending claims in the present application, and claims 1, 2, 5, 6, 9, 10, and 13-36 are currently under consideration. Applicants cancel, without prejudice, claims 18-20, 31, 33, 35, and 36. Applicants reserve the right to prosecute claims of similar or differing scope. Applicants add new claims 37-46. Support for the subject matter of these claims is found throughout the specification and previously pending claims. Exemplary support can be found in previously pending claim 20.

Applicants request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the previous office action.

1. Applicants note with appreciation that the amendments put forth on August 4, 2005 have been entered in full.
2. Applicants note with appreciation that any objections or rejections that were not expressly maintained in this Office Action have been withdrawn.
3. Claims 1, 2, 5, 6, 9, 10, 13-19, 21-25, 30, 32, and 34 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over US Patent No. 6,639,051 (the “‘051 patent”) in view of Ericson et al. and US Patent No. 4,816,567 (the “‘567 patent”). Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

Applicants maintain the arguments of record and contend that the combination of references fail to satisfy the criteria necessary for rendering the claimed invention obvious. Nevertheless, to expedite prosecution, Applicants have amended the claims to more particularly point out certain embodiments of Applicants’ invention. Specifically, Applicants have amended the claims to more particularly point out that the claimed method is directed to topical administration of the subject agents. Applicants’ amendments incorporate the subject matter of, for example, previously pending claim 20. Applicants note that previously pending claim 20 was not rejected as anticipated or obvious in view of the prior art. Applicants’ amendments are not in acquiescence to the rejection. Applicants reserve the right to prosecute claims of similar or differing scope in this or future applications.

The combination of references cited by the Examiner fail to teach or suggest methods involving topical administration of the subject agents. Given that the combination of references fail to teach or suggest the claimed subject matter, reconsideration and withdrawal of this rejection is respectfully requested.

4. Claims 1, 5, 9, 13-24, and 30-36 are rejected under 35 U.S.C. 112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

The basis of the rejection is that the epitopes for 5E1 and AP.G6 are allegedly unknown, and thus one of skill in the art cannot appreciate the metes and bounds of the claimed subject matter. Applicants respectfully disagree. The 5E1 antibody was developed in 1996 and has since been extensively used and studied (See, for example, Ericson et al., 1996; Pepinsky et al., 2000; enclosed herewith as Exhibits 1 and 2). Furthermore, the 5E1 antibody has been deposited and is available from the Developmental Studies Hybridoma Bank. Based on the literature and the accessibility of commercially available preparations of 5E1, one of skill in the art can readily assess the metes and bounds of the claimed subject matter. Accordingly, Applicants contend that claims directed to the use of 5E1 antibody are clear.

Applicants contend that the AP.G6 antibody is sufficiently described in the specification such that one of skill in the art can appreciate the metes and bounds of the claimed subject matter. The skilled artisan need not know the particular epitope to which AP.G6 binds to make and use the invention or to appreciate the scope of the claims. Nevertheless, to expedite prosecution, Applicants have amended the claims to exclude explicit reference to AP.G6. Applicants' amendments are not in acquiescence to the rejection. Applicants reserve the right to prosecute claims of similar or differing scope. In light of Applicants' amendments, reconsideration and withdrawal of this rejection is requested.

5. Claims 20 and 36 are rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to enable one of skill in the art to practice the claimed invention. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

The instant specification discusses in great detail that agents according to the present invention can be administered topically (See, for example, paragraphs 73, 109, 111, and 116). In fact, the specification recognizes that topical administration may be a particularly effective route of administration for treating conditions of epithelial cells and tissues (See, paragraph 73).

In doubting the enablement of the claimed invention, the Examiner cites a single publication that reported that some macrolides (though not others) did not effectively penetrate the skin when applied topically. Specifically, the cited reference reported that cyclosporine failed to effectively penetrate the skin when applied for the treatment of psoriasis. Based on the similarity in size between cyclosporine and antibodies, the Examiner posits that this reference undermines the enablement of methods of topically administering hedgehog antibodies. Applicants respectfully disagree.

The Examiner has cited a reference disclosing the use of a structurally and chemically distinct agent for the treatment of a particular inflammatory condition, and has alleged that such a distant reference casts doubt on the scope of enablement of the presently claimed invention. Applicants respectfully disagree. Applicants direct the Examiner's attention to EP 0991423 (the '423 patent; enclosed herewith as Exhibit 3). This issued European patent teaches topical administration of antibodies to IL-8 for the effective treatment of disorders of the skin. Applicants contend that the '423 patent demonstrates that antibodies can be effectively administered topically. Thus, contrary to the teachings of a reference using a structurally unrelated small molecule, one of skill in the art would have no reason to doubt the teachings of the present application in light of Applicants' disclosure and the state of the art with respect to topical administration of antibody preparations.

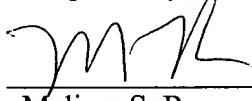
Applicants contend that the present claims are enabled throughout their scope. Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Please charge our Deposit Account No. 18-1945 in the amount of \$850.00 which includes the fees for a two-month petition for extension of time and two additional independent claims. Please charge any further fees due or credit any overpayments to **Deposit Account No. 18-1945, under order no. CIBT-P01-114.**

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Respectfully Submitted,



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